

32 and at least one of translational and oscillatory motion and said vibration resulting in a mixing action within said body lumen.

Please cancel claim 43.

33 sub C4 --44. (Added) A method of Claim 42 wherein said elongate vibratory motion catheter comprises a wire.--

REMARKS

Claims 38-43 are currently pending. The March 15, 2002, Office Action rejected claims 38-43. This Amendment cancels claims 41 and 43 without prejudice or disclaimer, amends claims 38-40 and 42, and adds claim 44. After entry of the foregoing amendments, claims 38-40, 42 and 44 (two independent claims; five total claims) remain pending in the application. Reexamination and reconsideration are respectfully requested.

Claim Rejections Under 35 U.S.C. §102(e)

Claims 38, 39 and 41-43 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,344,395, issued to Whalen et al. on September 6, 1994 (hereinafter "Whalen"). In particular, the Examiner stated, "Whalen discloses a catheter assembly having a source of mechanical motion which engages with an elongate member which comprises a wire. This motion source also provides different types of motion, including rotational and translational. This reference goes on further to describe a method of operation for the catheter assembly." Applicants respectfully traverse this rejection.

Whalen generally discloses an apparatus for intravascular cavitation which includes a catheter assembly 14 composed of a core wire 32, a distal tip 16, a wire support tube 34 and a particle removal sheath or damping sheath 36. (See column 6, lines 40-61.) The Whalen device also includes a driving apparatus 18, which is coupled to core wire 32 to provide oscillatory motion to core wire 32 and tip 16, thus causing cavitation at the location of tip 16.

Applicants' amended independent claim 38 recites, "A device for insertion into a body lumen useful for dissolution of obstructive material, the device comprising: a source of mechanical motion; and an elongate vibratory motion catheter having a proximal portion, a distal portion, and a longitudinal axis therebetween, wherein said proximal portion is matingly engageable with the source of mechanical motion, wherein said source of mechanical motion is configured to provide vibrational motion to the vibratory motion catheter, said vibrational motion including rotational motion about the longitudinal axis and at least one of translational motion and oscillatory motion."

Applicants' amended independent claim 42 recites, "A method of dissolution of obstructive material in a body lumen of a patient comprising: providing a source of mechanical motion coupled to an elongate vibratory motion catheter having a proximal portion, a distal portion, and a longitudinal axis therebetween; inserting said vibratory motion catheter into the body lumen of the patient such that said source of mechanical motion remains outside the patient's body; and activating said source of mechanical motion such that said source of mechanical motion causes vibration of said vibratory motion catheter along said longitudinal axis, said vibration including rotational motion about the longitudinal axis and at least one of translational and oscillatory motion and said vibration resulting in a mixing action within said body lumen."

Although the Office Action states that Whalen "provides different types of motion, including rotational and translational," Applicants respectfully submit that Whalen does not, in fact, provide for rotational motion. Such rotational motion, described in claims 38 and 40, in the present specification, and in Figs. 9 and 10 of the present application, may provide additional advantages in mixing or performing similar functions within a body lumen.

Applicants submit, therefore, that each and every element of independent claims 38 and 42 are not disclosed, taught or suggested by Whalen. Accordingly, claims 38 and 42 (and claim 39 which depends from claim 38) are not anticipated by Whalen, and Applicants respectfully request the withdrawal of the rejection of claims 38, 39 and 42 under 35 U.S.C. § 102(e).

Claims Rejected Under 35 U.S.C. § 103(a)

Claim 40 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Whalen in view of U.S. Patent No. 5,370,651, issued to Summers on December 6, 1994 (hereinafter "Summers"). In particular, the Examiner stated, "...it would have been obvious to one skilled in the art at the time of the invention to modify Whalen's device with the teaching of Summers in order to provide a device for dislodging obstructive materials using the motion of a wire that has greater vibrational motion at it's treatment end than at its attachment end, engaging with the shaft extension." Applicants respectfully traverse this rejection.

Summers generally describes a distal atherectomy catheter including a motor 22 coupled to a drive shaft 30 which drives a flexible drive wire 46, connected to a cutter 86, within a catheter tube 12. The drive shaft 30 provides motion to the cutter 86, but not to the catheter tube 12. The Summers device also requires a brace 32 and a bushing 34 to minimize vibration of the shaft 30. Summers does not teach or suggest that the brace 32 or bushing 34 varies vibration along the catheter tube 12.

Applicants' amended claim 40 recites, "A device of Claim 38 wherein said source of mechanical motion is configured to provide said vibrational motion to said elongate vibratory motion catheter such that said vibrational motion is greater near the distal end of said elongate vibratory motion catheter than at the proximal end of said elongate vibratory motion catheter."

Applicants submit that even if the proposed combination were made, the invention of claim 40 would not be obtained. First, as described above, Whalen does not disclose or suggest "rotational motion about the longitudinal axis," as recited in claim 38, from which claim 40 depends. Second, neither Whalen nor Summers discloses, teaches or suggests "vibrational motion [that] is greater near the distal end of said elongate vibratory motion catheter than at the proximal end of said elongate vibratory motion catheter."

Applicants further submit that the prior art of record contains no suggestion or motivation to combine the references as proposed by the Examiner. In fact,

there is at least an implication that Whalen and Summers teach away from a combination of the two references, because it would likely be disadvantageous to combine a device with a cutter at its distal tip (Summers) with a device that oscillates a distal tip (Whalen). Such a combination could cause significant damage to a body lumen, such as a blood vessel, by oscillating the cutter into a wall of the lumen.

For the above reasons, Applicants respectfully request the withdrawal of the rejection of claim 40 under 35 U.S.C. § 103(a).

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

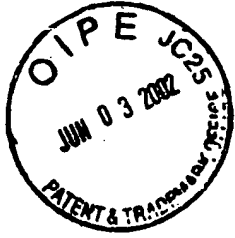
If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claims 1-37 were previously canceled.

38. (Amended) A device for insertion into a body lumen useful for dissolution of obstructive material, the device comprising:
a source of mechanical motion; and
an elongate **[member]** vibratory motion catheter having a proximal portion, a distal portion, and a longitudinal axis therebetween, wherein said proximal **[end]** portion is matingly engageable with the source of mechanical motion,
wherein said source of mechanical motion is configured to provide vibrational motion to the vibratory motion catheter, said vibrational motion including rotational motion about the longitudinal axis and at least one of translational motion and oscillatory motion.

39. (Amended) A device of Claim **[1]** 38 wherein said elongate **[member]** vibratory motion catheter comprises a wire.

40. (Amended) A device of Claim **[1]** 38 wherein said source of mechanical motion is **[engaged to the proximal end of said elongate member to cause a vibrational motion along the longitudinal axis of]** configured to provide said vibrational motion to said elongate **[member]** vibratory motion catheter such that said vibrational motion is greater near the distal end of said elongate **[member]** vibratory motion catheter than at the proximal end of said elongate **[member]** vibratory motion catheter.

Please cancel claim 41.

42. (Amended) A method of dissolution of obstructive material in a body lumen of a patient comprising:

providing a source of mechanical motion coupled to an elongate
[member] vibratory motion catheter having a proximal portion, a distal portion, and a
longitudinal axis therebetween, [said elongate member comprising a wire];

inserting said [wire] vibratory motion catheter into the body lumen of [a]
the patient such that said source of mechanical motion remains outside the patient's body;
and

activating said source of mechanical motion such that said source of
mechanical motion causes vibration of said [wire] vibratory motion catheter along said
longitudinal axis, said vibration including rotational motion about the longitudinal axis
and at least one of translational and oscillatory motion and said vibration resulting in a
mixing action within said body lumen.

Please cancel claim 43.

--44. (Added) A method of Claim 42 wherein said elongate vibratory
motion catheter comprises a wire.--

inserting said vibratory motion catheter into the body lumen of the patient such that said source of mechanical motion remains outside the patient's body; and activating said source of mechanical motion such that said source of mechanical motion causes vibration of said vibratory motion catheter along said longitudinal axis, said vibration including rotational motion about the longitudinal axis and at least one of translational and oscillatory motion and said vibration resulting in a mixing action within said body lumen.

Please cancel claim 43.

--44. (Added) A method of Claim 42 wherein said elongate vibratory motion catheter comprises a wire.--